**Remarks/Arguments:**

I. Status of Application and New Claims

In the Office Action, claims 1-8 rejected. In the present response, claims 1 and 2 are cancelled, claims 3 and 5 - 8 are amended, and new claims 9-13 are added. Newly added claims 9-13 are fully supported by the specification. Specifically, Examples 1 and 2 set forth the composition of the hyperimmunizing vaccine, and the infection-free condition of the subject animal (mice). Specification, page 14, lines 8-25 and page 15, lines 23-25. Accordingly, there is no issue of new matter. Claims 3-13 are pending.

The newly added claims are directed to a method in which egg or egg product from hyperimmunized animals is administered to a subject animal to treat diarrheal symptoms. The claims provide that the hyperimmunized animal is vaccinated with immunogens (thus generating antibodies to those immunogens in the egg), and that the subject animal is free from infection related to those immunogens. For example, an animal hyperimmunized against salmonella produces egg product which is administered to a subject animal that is NOT infected with salmonella in treating diarrheal symptoms of the subject animal. The claim clearly distinguishes from prior art disclosing passive immunization methods, as the immunization of the egg-producing animal is unrelated to the condition of the subject animal.

Additionally, the newly added claims do not recite specific components of the egg-product, and focus on the method of treating diarrheal symptoms in non-infected animals using hyperimmunized egg product, without requiring the hyperimmunization to be directed against pathogens responsible for causing the diarrheal symptoms.

II. Rejections under 35 U.S.C. § 112, first paragraph

Claims 1-8 were rejected as lacking adequate written description, and were also rejected for lack of enablement. The applicants respectfully traverse the rejections as applied to the pending claims. Claim 9 recites "[a] method for treating and preventing diarrheal symptoms in a subject animal, the method comprising

hyperimmunizing an egg-producing animal, collecting an egg or egg product from the hyperimmunized egg-producing animal, and administering an effective amount of the egg or egg product to the subject animal, wherein hyperimmunizing the egg-producing animal comprises treating the egg-producing animal with a vaccine comprising at least one immunogen, and wherein the subject animal is free of infection from the immunogen.." The other pending claims depend, either directly or indirectly from claim 9 or 10.

According to the Guidelines for Examination of Patent Applications Under 35 U.S.C. 112(1), "Written Description" Requirement, (hereafter "Guidelines"), an application must disclose the claimed invention in sufficient detail to enable a person of ordinary skill in the art to make and use the claimed invention to satisfy the written description requirement. The description must show that the applicant was in possession of the claimed invention at the time of filing. *There is no statutory basis to require disclosure of why an invention works*. 66 Fed. Reg. 4, 1099, 1103, (Jan. 5, 2001) (emphasis added).

The application sets forth the claimed invention in sufficient detail to enable one skilled in the art to make and use the invention. Specifically, the application sets forth how to 1) hyperimmunize an egg-producing animal (page 6, line 5-page 10, line 25 and Example 1, page 13, line 27-page 15, line 15); 2) collect egg or egg product from the hyperimmunized egg (page 10, line 26- page 11, line 30 and page 15, lines 9-15); and 3) administer an effective amount of the egg or egg product (page 12, line 21-page 13, line 21, and Example 2, page 15, line 19-page 46, line12). Because the specification fully describes each of acts in the claimed process, it satisfies the written description requirement.

Furthermore, a person of ordinary skill in the art is able to make and use the invention. The application sets forth specific examples of the process for treating diarrheal symptoms, providing detailed instructions for producing a hyperimmunized egg-producing animal, collecting egg product, and administering the egg or egg product. Because the application illustrates each of the component steps in the claimed process, a skilled artisan is equipped to perform the invention.

The Office Action asserts that the written-description and enablement requirements are not met because the application does not identify anti-diarrheal agents. Because the claims are directed to a process of treating diarrhea, the claim does not require the identification of the anti-diarrheal agents that are present in the egg-product produced from a hyperimmunized animal. The applicants have no obligation to reveal **why** an invention works, and the identity of anti-diarrheal agents is not necessary for one to make and use the invention. Nor is the identity of such agents a requirement to establish that the inventors had possession of the process for treating diarrhea. The application provides data illustrating that the inventors were able to treat and prevent diarrhea in mice using the claimed method. Page 16, line 14-page 18, line 25.

In regards to claims 3 and 5, the Office Action stated that the application did not teach mixtures of immunogens for immunizing the egg-producing animal. In response, the applicants note that the specification teaches that the hyperimmune state is preferably produced by "immunogen or combination or immunogens," and that hyperimmunozation is preferably achieved by "multiple exposures to multiple immunogens." One of ordinary skill in the immunization art would understand that combinations of immunogens can be administered in a mixture to induce an immune response.

For these reasons, the applicants submit that the application satisfies the written description and enablement requirements of 35 U.S.C. § 112(1), and respectfully request withdrawal of the rejection.

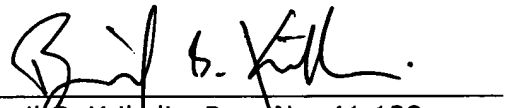
III. Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-8 were rejected under 35 U.S.C. § 112(2) as being indefinite. Specifically, the Office Action noted language in claim 1 as unclear. Claim 1 has been cancelled, rendering the rejection moot.

IV. Conclusion

The rejections under 35 U.S.C. § 112 should all be withdrawn. Favorable action is earnestly solicited. Finally, the Examiner is invited to call the applicants' undersigned representatives if any further amendment will expedite the prosecution of the application or if the Examiner has any suggestions or questions concerning the application or the present Response. In fact, if the claims of the application are not believed to be in full condition for allowance, for any reason, the applicants respectfully request the constructive assistance and suggestions of the Examiner in drafting one or more acceptable claims pursuant to MPEP § 707.07(j) or in making constructive suggestions pursuant to MPEP § 706.03 so that the application can be placed in allowable condition as soon as possible and without the need for further proceedings.

Respectfully submitted,



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